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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,817	05/09/2001	Jochen Wolffgramm	MRI-1	4970

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,817	WOLFFGRAMM, JOCHEN	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10,14-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *2-4,7-10 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,14-20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2004 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed October 20, 2004, and amendment and response to the Final Office Action (mailed April 20, 2004), filed October 20, 2004 wherein claims 5-6, 14-20 and 25 have been amended, and claims 1, 11-13, 21, and 26 are cancelled.

Currently, claims 2-10, 14-20 and 22-25 are pending in this application.

As recorded in the previous Office Action April 20, 2004, Claims 2-4, 7-10 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 5-6, 14-20 and 25 as amended now are examined on the merits herein.

Applicant's remarks, filed October 20, 2004 with respect to the rejection made under 35 U.S.C. 112 first paragraph for inserting new matter of record stated in the

Office Action dated April 20, 2004 has been fully considered and is found persuasive to remove this rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment, filed October 20, 2004 with respect to the rejection made under 35 U.S.C. 112 for indefinite expressions "a pharmacodynamic equivalent thereof" of record stated in the Office Action dated April 20, 2004 has been fully considered and is found persuasive to remove this rejection since this recitation "a pharmacodynamic equivalent thereof" has been removed. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 are rejected under 35 U.S.C. 112, second paragraph, for indefinite expressions, "a high dose" for reasons of record stated in the Office Action dated April 20, 2004.

Applicant's argument filed October 20, 2004 with respect to this rejection made under 35 U.S.C. 112, second paragraph in the previous Office Action have been fully considered but are not deemed persuasive since the specification, i.e., page 20-22, fails to define clearly what is "a high dose" for the addictive drug.

The following is new rejection(s) necessitated by Applicant's amendment filed on October 20, 2004, wherein the limitations in the amended claims have been changed, i.e., the elected invention of species (1) opioid dependency and (2) a pharmaceutical composition comprising an opioid and prednisolone submitted May 2, 2003, have been deleted from the claims.

Therefore, the prior art rejections under 35 U.S.C. 103(a) of record in the previous Office Action April 20, 2004 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-6, 16-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capasso et al. (XP-002100184, PTO-1449 of record) or Applicant's admission regarding the prior art in the specification (see page 8,11-12).

Capasso et al. teach that the instant preferred corticosteroid receptor agonist, dexamethasone, is capable of reducing the psychomotor stimulant effects induced by cocaine and amphetamine in mice (see abstract), and the testing results by co-administering dexamethasone in 0.1-1.0-10 mg/kg/i.p. (within the instant claim since a standard person weight is 70 kg, the range of effective amounts of dexamethasone is

0.1 mg/kg X 70 kg =7 mg, to 1.0 mg/kg X 70 kg = 70 mg), and cocaine in 10 mg/kg/i.p. or amphetamine in 5 mg/kg/i.p. to mice (see page 1066, 4th paragraph) suggest that dexamethasone may play an important role on the treatment of cocaine and amphetamine abuse (see abstract, page 1068-1069).

It is noted that Applicant clearly admits and acknowledge the above teaching of Capasso et al. by citing the reference in the specification (see page 8 line 18-21, page 11 line 9-13).

Capasso et al. do not expressly disclose a kit comprising dexamethasone in the first receptacle, and cocaine or amphetamine in combination with dexamethasone in the in the second receptacle.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation by putting dexamethasone in the first receptacle, and cocaine or amphetamine in combination with dexamethasone in the in the second receptacle of a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation by putting dexamethasone in the first receptacle, and cocaine or amphetamine in combination with dexamethasone in the in the second receptacle of a kit, since, most importantly, the instant preferred corticosteroid receptor agonist, dexamethasone, is known to be useful in the treatment of cocaine and amphetamine abuse by reducing the psychomotor stimulant effects

induced by cocaine and amphetamine in mice, through co-administering dexamethasone in the known effective amounts, and cocaine in 10 mg/kg/i.p. or amphetamine in 5 mg/kg/i.p. to mice, according to Capasso et al. Thus, the critical and essential elements in the claims herein are clearly taught by the prior art.

As discussed in the previous Office Action, using a kit, a container, or a patient pack are all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication.

Claims 5-6, 14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caggiula et al.

Caggiula et al. teach that both acute and chronic corticosteroid (glucocorticoids or corticosterone) administration decrease, some of the physiological and behavioral effects of nicotine. The findings by Caggiula, et al. suggested that co-administering corticosteroid such as corticosterone and nicotine in rats, is useful in treating the addiction of nicotine (see abstract and the entire article).

Caggiula et al. do not expressly disclose the employment of a kit comprising corticosterone in the first receptacle, and nicotine in combination with corticosterone in the in the second receptacle.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation by putting corticosterone in the first

receptacle, and nicotine in combination with corticosterone in the in the second receptacle of a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a kit to store the known composition, a pharmaceutical preparation, or a pharmaceutical formulation by putting corticosterone in the first receptacle, and nicotine in combination with corticosterone in the in the second receptacle of a kit, since the instant preferred corticosteroid receptor agonist, corticosterone, is known to be useful in the treatment of nicotine addiction in rats, through co-administering corticosterone in the known effective amounts, and nicotine, according to Caggiula et al. Thus, the critical and essential elements in the claims herein are clearly taught by the prior art.

Again, using a kit, a container, or a patient pack are all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication.

Claims 5-6, 14-20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capasso et al. or Caggiula et al. in view of Applicant's admission regarding the prior art in the specification (see page 12-13) and Peyman (WO 9842275, of record).

The same disclosure of Capasso et al. or Caggiula et al. has been discussed above.

Capasso et al. or Caggiula et al. do not expressly disclose that the addictive drug is cannabinoid or crack or MDMA. Capasso et al. or Caggiula et al. do not expressly disclose that the preferred corticosteroid receptor agonist is prednisolone.

Note that Applicant clearly admits and acknowledges the teachings of Wolffgram and Heyne, (1995) that "it was found that administration of corticosteroids can change addictive behaviour successfully, if the administration of corticosteroids is combined with a preferably highly-dosed administration of an addictive drug" by citing the review article by Wolffgramm and Heyne, 1995, in the specification (see page 12 line 25 to page 13 line 9).

Peyman discloses that cortisol, cortisone, prednisolone, and dexamethasone are known corticosteroids or glucocrticoids (see page 8 line 27 to page 9 line 1, and claims 1-2 and 15-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ corticosteroids or glucocrticoids such as prednisolone, corticosterone and dexamethasone in treating the addiction by cannabinoid or crack or MDMA.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ corticosteroids or glucocrticoids such as prednisolone, corticosterone and dexamethasone in treating the addiction by cannabinoid or crack or MDMA, since the administration of corticosteroids including prednisolone, corticosterone and dexamethasone is combined with a preferably highly-dosed administration of an addictive drug, is known to be useful in treating drug addiction in

animals, according to the prior art. Thus, the critical and essential elements in the claims herein are clearly taught by the prior art.

Note the instant claims are not drawn to any method of administration but merely a kit comprising a known pharmaceutical composition, preparation, or formulation. Therefore, the sequence of administration of the addictive drug and the corticosteroid is not considered to be a limitation to a kit.

Applicant's arguments filed October 20, 2004 with respect to the rejections made under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
January 26, 2005